REMARKS

Applicants acknowledge that claims 37 to 39, 41 to 43, 45 to 57, 61 to 72 and 74 to 81 have been withdrawn in view of a USPTO restriction requirement.

Claims 59 and 60 and new claims 82 to 85 are pending. As previously reported, these claims are substantively the same as claims 54 and 55 of US Patent 6,572,576 ('576 Patent), which are presented below:

> 54. A leak detector for a sterile contiguous fluid line for infusing a patient, the fluid line including a draw line connectable to at least one patient access and a return line connectable to said at least one patient access, said detector comprising:
>
> a portion adapted to be interoperable with a pump actuator such that fluid may be conveyed therethrough;
>
> a filter, or filter connectors to permit connection to a filter, to complete a closed fluid circuit joining said draw and return lines;
>
> at least a wetted portion of a device configured to generate a negative pressure in said return line, whereby a flow through said return line may be reversed.
>
> 55. A detector line as in claim 54, wherein said device configured to generate a negative pressure is further configured to reverse a flow in both said return line and said draw line.

Claims 59 and 60 should be allowed for the same reasons that the USPTO allowed claims 54 and 55 in the '576 Patent. Allowance of claims 59 and 60 is respectfully requested so that an interference may be declared between this application and the '576 Patent.

The rejection of claims 59 and 60 as lacking an enabling disclosure because they omit a leak detector structure is traversed. The copied claims 54 and 55 of the '576

Patent do not recite a blood leak sensor. It is respectfully requested that claims 59 and 60 not be required to recite a leak sensor so that they may closely track the actual language of claims 54 and 55 of the '576 Patent. Further, the claims recite an operational device that is fully enabled by the specification. The specification does not indicate that a leak detector is needed for the reversing blood pump recited in claims 59 and 60. The enablement rejection should be withdrawn.

In an further effort to overcome the rejection, new claims 82 to 85 have been added that are substantively the same as claims 54 and 55 of the '576 Patent, except that claims 82 and 83 expressly recite a blood leak sensor and the preamble of claims 84 and 85 recite a blood flow direction device.

The rejection of claims 59 and 60 as being anticipated by Kenley et al (US Patent 5,690,831) is traversed. An anticipatory prior art reference must actually or inherently disclose an invention. The standard for an anticipatory reference is:

> A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.

SmithKline Beecham Corp. v. Apotex Corp., 74 USPQ2d 1398, 1406 (Fed. Cir. 2005)(citations omitted).

Claim 59 requires that the device generate a negative pressure in the blood return line, whereby a flow through the return line may be reversed. Kenley et al. do not expressly disclose the reversal of blood flow in an extracorporeal blood circuit or

operating the blood pump to create a negative pressure in the blood line. Further, the Kenley pump may be operated without reversing flow or generating a negative pressure. It is not inherent that the Kenley pump reversed the blood flow in a blood circuit. Accordingly, there is no anticipation.

The rejection applies Kenley et al. as an anticipatory reference because the Kenley pump is purportedly capable of operating as the claimed device.[1] The rejection is not supported by the test for anticipation stated in *SmithKline Beecham Corp.* That a device is "capable of" operating in a certain configuration or matter does not necessarily result in the device being an anticipation. *America LP v. GSE Lining Technology Inc.*, 72 USPQ2d 1685, 1688-89 (Fed. Cir. 2004)(In finding no anticipation the court stated that "GSE's argument [for anticipation] that the [prior art] Gundle die was capable of performing the claimed method is largely premised on the hindsight that its choker slides were able to achieve an objective they were not originally designed to do.") The anticipation rejection should be withdrawn because there is no expressed or inherent disclosure in Kenley et al. to reverse blood flow.

[1] Kenley does not state that the pump motor has a reverse mode. It is not certain that Kenley is capable of operating in a reverse mode.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone the undersigned attorney. Prompt reconsideration and allowance of this application would be appreciated.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____
Jeffry H. Nelson
Reg. No. 30,481

JHN:glf
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100